

In re National Prescription Opiate Litigation: MDL 2804
Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Memorandum in Opposition to Distributor Defendants' Motion for Summary Judgment on Plaintiffs' Negligence Per Se Claims

Opposing Parties: Plaintiffs Summit County and Cuyahoga County

Issue 1: Have Plaintiffs established that they are intended beneficiaries of the federal Controlled Substances Act ("CSA")?

Answer: Yes. Defendants assert that the Court's order dismissing the negligence per se claims of the Muscogee (Creek) Nation and The Blackfeet Tribe of the Blackfeet Indian Nation (Dkt. No. 1680) applies with equal force to Plaintiffs. But Ohio counties are not the same as sovereign tribes, and the Court's analysis of the tribal negligence per se claims did not address public entities that, like Plaintiffs, conduct law enforcement activities. Congress expressly stated that one of its primary goals in enacting the CSA was to strengthen law enforcement in order to protect communities from drug abuse. Testimony and documents produced in the course of discovery confirm that Plaintiffs expend considerable resources in investigating and prosecuting drug crimes, including crimes involving prescription opioids. This evidence establishes that Plaintiffs are intended beneficiaries of the CSA by virtue of their efforts to enforce drug laws for the safety of their communities.

Moreover, even assuming the Court were to conclude that Congress did not intend for the CSA to benefit Plaintiffs, evidence of Defendants' statutory and regulatory violations is still admissible in support of Plaintiffs' common law negligence claims. The Ohio Supreme Court declared that such violations may always be used as evidence of negligence, even where the standard for negligence per se is not met. As a result, granting Defendants' motion will not streamline the trial or impact the nature of evidence heard by the jury.

Filing Date: June 28, 2019
Response Date: July 31, 2019
Reply Date: August 16, 2019

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION

OPIATE LITIGATION

This document relates to:

Track One Cases

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO
DISTRIBUTOR DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON
PLAINTIFFS' NEGLIGENCE PER SE CLAIMS**

July 31, 2019

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INTRODUCTION

Distributors' Motion for Summary Judgment, which seeks to preclude Plaintiffs from arguing that Distributors' statutory violations constitute negligence per se, is based on a flawed understanding of the federal Controlled Substances Act ("CSA"). Distributors' central contention is that Plaintiffs, as public entities, are not intended beneficiaries of the CSA, and therefore the doctrine of negligence per se does not apply. This contention is premised entirely and uncritically on the Court's dismissal of the negligence per se claims brought by the Muscogee (Creek) Nation and The Blackfeet Tribe of the Blackfeet Indian Nation (collectively, "Tribes") (Dkt. No. 1680). However, Ohio counties are not the same as sovereign tribes. The legislative history of the CSA, as well as interpretive case law, demonstrates that Congress intended to benefit not only individual members of the public, but also entities like Plaintiffs that are charged with enforcing drug laws for the protection of their communities. Plaintiffs' law enforcement duties place them squarely within the class of persons that were intended to benefit from the passage of the CSA, and for this reason Distributors' Motion must fail.

The motion should also be denied because it will not streamline or shorten the trial and thus deciding the motion now does not serve the interests of judicial economy. In addition to the formal doctrine of negligence per se, which allows for the violation of a statute to substitute for proof of the existence and breach of a duty of care, Ohio law also allows a plaintiff to introduce evidence of statutory duties and violations to inform the scope of the common law duty of reasonable care. As a result, even if the Court were to extend its tribal ruling to the county plaintiffs here, there would be little to no effect on the trial because Plaintiffs are still permitted to introduce evidence of statutory violations in support of their traditional negligence claim. The motion should therefore be denied because questions regarding the permissible scope of Plaintiffs' negligence claims are more appropriately addressed at trial after development of a full evidentiary record.

ARGUMENT

I. DEFENDANTS' MOTION DOES NOT SEEK JUDGMENT ON PLAINTIFFS' NEGLIGENCE CLAIMS

The operative complaints for both Summit County and Cuyahoga County advance a single claim for “negligence” among their eleven causes of action (Dkt. No. 1466 at 315; Dkt No. 1631 at 335). Neither complaint asserts a standalone cause of action for negligence per se. Rather, the complaints allege negligence per se as an alternative to the traditional negligence claim that is based on duties recognized at common law. Distributors’ Motion seeks summary judgment only with respect to claims based on negligence per se and does not address Plaintiffs’ negligence claims.

The effort to strike Plaintiffs’ negligence per se claims must be evaluated in the broader context of a traditional negligence claim. Under Ohio law, a negligence claim contains three distinct elements: (1) a duty owed by the defendant to the plaintiff to conform to a certain standard of conduct, (2) the defendant breached that duty, and (3) the breach of the duty proximately caused the plaintiff’s injury. *Cromer v. Children’s Hosp. Med. Ctr. of Akron*, 29 N.E.3d 921, 928-929 (Ohio 2015). In a traditional negligence claim, the plaintiff is first required to establish the nature and extent of the duty owed by the defendant, typically by demonstrating the standard of care that a reasonably prudent person would exercise under the same or similar circumstances. *See Mussivand v. David*, 544 N.E.2d 265, 270 (Ohio 1989). The plaintiff must then establish that the defendant’s conduct constitutes a breach of that standard of care.

Under the doctrine of negligence per se, however, the first and second negligence elements are reduced to a single inquiry: did the defendant violate a statute? An affirmative answer means that the plaintiff is relieved from having to establish either the existence of a duty or the breach of that duty. As the Ohio Supreme Court explained almost a century ago:

The distinction between negligence and ‘negligence per se’ is the means and method of ascertainment. The first must be found by the jury from the facts, the conditions, and circumstances disclosed by the evidence; the latter is a violation of a specific requirement of

law or ordinance; the only fact for determination by the jury being the commission or omission of the specific act inhibited or required.

Swoboda v. Brown, 196 N.E. 274, 274 (1935).

The distinction in how statutory violations are treated in negligence per se and traditional negligence claims is therefore best understood as a matter of evidentiary presumptions. In a negligence claim, a defendant's statutory violations constitute rebuttable evidence of a breach of the standard of care. See § C, *infra*. In a negligence per se claim, however, the violations are conclusive evidence of such a breach, and the only remaining question is whether the breach was the proximate cause of the plaintiff's injury. *Chambers v. St. Mary's Sch.*, 697 N.E.2d 198, 201 (Ohio 1998).

II. PLAINTIFFS ENFORCE DRUG LAWS FOR THE SAFETY OF THEIR COMMUNITIES AND ARE THEREFORE INTENDED BENEFICIARIES OF THE CSA

As described below, the CSA was intended to protect communities, not just individual members of the public. A primary reason Congress enacted the CSA was to ensure the safety of communities by providing more effective means for local governments to enforce the law concerning drug abuse prevention and control. Plaintiffs indisputably enforce various drug laws, including laws specifically designed to prevent the diversion of opioids. *See, e.g.*, Ohio Rev. Code §§ 2925.03, 2925.23. Plaintiffs are therefore intended beneficiaries of the CSA.

The assumption lying at the heart of Defendants' Motion is that the Court's recent dismissal of the Tribes' negligence per se claims effectively disposed of all similar claims by public entities. Yet such a simplistic view fails to account for potential differences between governmental entities and how these differences impact the analysis of a given plaintiff's negligence per se claim. Moreover, the posture of the Court's ruling suggests that the Tribes may have failed to highlight key aspects of the

legislative history of the CSA.¹ Thus, the Court did not receive full briefing regarding the persons and entities that Congress intended to benefit through passage of the Act.

Plaintiffs acknowledge the Court's ruling that the CSA was intended to benefit "individual members of the public." Dkt. 1680 at 24. But the Act's intended benefits were not limited to individual citizens. Plaintiffs respectfully suggest that Congress intended for a broader class of persons to benefit from passage of the CSA, as evidenced both by the legislative history and courts interpreting the CSA. In particular, Congress expressly intended to benefit communities in addition to specific individuals. In enacting the CSA, Congress specifically articulated a concern for the "health and general welfare of the American people." 21 U.S.C. § 801(1)-(2). In interpreting the Act, courts have found that "[t]he statutory language, as well as the legislative history, unequivocally [sic] establishes that Congress intended to equate traffic in drugs with a danger to the *community*." *United States v. Strong*, 775 F.2d 504, 506 (3d Cir. 1985) (emphasis supplied); *see also* H.R. Rep. 91-1444, 1970 U.S.C.C.A.N. 4566, 4567, 1970 WL 5971 (noting the dangers that controlled substances pose to the "safety of the community").

Protecting the community as intended by the CSA can only be done by the government. "Whether the government has a compelling interest in preventing drug abuse can hardly be disputed." *United States v. Israel*, 317 F.3d 768, 771 (7th Cir. 2003). Indeed, "[f]ew problems affecting the health and welfare of our population, particularly our young, cause greater concern than the escalating use of controlled substances." *United States v. Mendenhall*, 446 U.S. 544, 561 (1980).

¹ As the Court observed, "the Muscogee R&R and the Blackfeet R&R declined to address Defendants' arguments regarding negligence per se because the R&Rs found that Plaintiffs sufficiently pled a common law duty." Dkt. No. 1680 at 23. In their briefing regarding Defendants' Motions to Dismiss, the Tribes asserted they were intended beneficiaries of the CSA based solely on their status as members and/or representatives of the "public." Dkt. Nos. 1624 at 9; 1017 at 103; 1008 at 96. The Tribes never argued that they had any law enforcement responsibilities or other duties that compelled them to protect the community from the dangers of controlled substances.

In keeping with the desire to benefit the community as a whole, the CSA was intended “to facilitate law enforcement, drug research, educational and related control facilities.” *Gooding v. United States*, 416 U.S. 430, 449 (1974) (quoting S. Rep. No. 91-613, at 3 (1969)). The legislative history emphasizes this aspect of the CSA, and it is clear the Act was drafted to “strengthen existing law enforcement authority in the field of drug abuse.” Pub. L. No. 91-513, 84 Stat. 1236 (1970) (codified at 21 U.S.C. §§ 801–904). Congress declared that a “principal purpose” of the CSA was “providing more effective means for law enforcement aspects of drug abuse prevention and control.” H.R. Rep. 91-1444, 1970 U.S.C.C.A.N. 4566, 4567, 1970 WL 5971; *see also United States v. Woods*, 568 F.2d 509, 513 (6th Cir. 1978) (Congress “was no doubt intent upon strengthening the enforcement of existing drug laws”); *United States v. Steinberg*, 525 F.2d 1126, 1133 (2d Cir. 1975). An explicit legislative goal of the CSA was to “significantly reduce the widespread diversion of [controlled substances] out of legitimate channels into the illicit market.” H.R. Rep. 91-1444, 1970 U.S.C.C.A.N. 4566, 4567, 1970 WL 5971.

Congress therefore specifically intended to include local governmental entities that are charged with safeguarding their communities as direct beneficiaries of the federal CSA. As demonstrated below, Plaintiffs are indisputably a member of this class because they carry out law enforcement activities that directly relate to drug abuse and diversion.

i. Summit County

The responsibility for enforcement of drug laws requires coordination between federal, state, county and local government police forces. In Summit County, these forces work closely together on a combined multi-jurisdictional drug task force known as the Summit County Drug Unit. The Drug Unit is commanded by a member of the Summit County Sheriff’s Office. The Drug Unit’s former

Commander, Hylton Baker, testified that the job of the unit was “to enforce drug laws and inform the public and keep them safe.”²

The Drug Unit’s 2009 Annual Report reflects drug arrests of individuals for a variety of substances and demonstrates that, during the reporting period, arrests for pharmaceutical drugs outpaced those for heroin.³ By the time the Summit County Sheriff’s Office 2017 Annual Report was issued, the need for targeted enforcement of drug laws to combat the opioid epidemic was front and center.⁴ The record is replete with examples of the Summit County Drug Unit’s enforcement of drug laws through investigation and arrest.⁵

In keeping with the multi-jurisdictional nature of drug investigations, Summit County Sheriff’s Office has two detectives who are assigned to the United States Drug Enforcement Agency (“DEA”) to work on drug investigations in Summit County.⁶ The Sheriff’s Office also has a deputy assigned to the DEA’s Tactical Diversion Squad for the specific purpose of enforcing laws against pill diversion.⁷ These assignments are in addition to the members of the Summit County Sheriff’s Office whose responsibilities include drug enforcement.

The Summit County Prosecutor’s Office is likewise significantly involved in the enforcement of drug laws in the county. Brad Gessner, Summit County Prosecutor, testified that his introduction

² Hylton Baker Dep. (12/19/18), Dkt. # 1956-10 at 100:23-101:24.

³ Ex. 1, 2009 Annual Report of The Summit County Drug Unit, SUMMIT_000830645.

⁴ Ex. 2, Excerpt of Summit County Sheriff’s Office 2017 Annual Report, SUMMIT_000830451 (“Our Operations Division continues to do their best in combating the opioid crisis all counties in Ohio have been experiencing. I would like to commend our Patrol and Detective Bureaus, along with our Drug Unit for their proactive approaches in dealing with these illicit activities, as well as their investigative skills,” SUMMIT_000830454).

⁵ See, e.g., Ex. 3, SUMMIT_001843287 (Individual arrested and charged with 2 counts of Deception to Obtain); Ex. 4, SUMMIT_001839815 (individual charged with Trafficking in Drugs (Oxycontin, Schedule II); Ex. 5, SUMMIT_000023798 (Summit County Drug Unit had 101 Drug violation arrests during the first six months of 2006 [SUMMIT_000023799]); Ex. 6, Excerpt of Drug Threat Assessment, SUMMIT_000023567 (“In the past three years, officers of the Summit County Drug Unit have arrested more than 400 patrons for trafficking, use and possession of illegal drugs.” [SUMMIT_000023572]).

⁶ Matthew Paolino Dep. (12/5/18), Dkt. # 1969-1 at 64:14-66:1.

⁷ *Id.* at 61:2-11.

to the county's drug enforcement efforts came shortly after he joined the Summit County Prosecutor's Office in 2001 when he "tried [his] first case of prescription drug abuse in Summit County."⁸ He noted that the prosecution of heroin and fentanyl dealers had become a priority for his office "based on the number of deaths occurring, based on the number of overdoses occurring."⁹

ii. Cuyahoga County

Similar to Summit County, many of the drug enforcement activities of Cuyahoga County are part of a larger multi-jurisdictional effort in the county. The Cuyahoga County Sheriff's Office has two deputies who are assigned to the DEA and work on drug task forces.¹⁰ These assignments are in addition to the drug investigation and enforcement activities that detectives in the Sheriff's Office perform on a routine basis.¹¹

James Gutierrez, a prosecutor for Cuyahoga County, testified to his significant involvement in drug prosecutions, including the illegal use of prescription opioids.¹² Mr. Gutierrez prosecuted and obtained convictions against doctors who prescribed excessive amounts of opioids.¹³ Cuyahoga County prosecutors also investigated pharmacies and pharmacists regarding the diversion of opioids.¹⁴ Indeed, there have been thousands of drug prosecutions by Cuyahoga County over the last 15 years involving the improper use of opioids.¹⁵

The foregoing evidence confirms the role of Summit and Cuyahoga counties in enforcing laws regarding opioids in order to protect their communities from the dangers of drug abuse. These

⁸ Brad Gessner Dep. (12/3/18), Dkt. # 1962-9 at 162:1-10.

⁹ *Id.*, 28:11-21

¹⁰ Ex. 7, Donald Gerome Dep. (11/14/18) at 64:15-65:2

¹¹ *Id.*, 79:2-80:19.

¹² James Gutierrez Dep. (1/31/19), Dkt. # 1962-16 at 29:6-30:1; 70:5-71:3.

¹³ *Id.* at 110:10-111:8; 135:11-25.

¹⁴ *Id.* at 185:8-21.

¹⁵ *Id.* at 24:8-25:15.

activities place the counties squarely among the class of persons that the CSA was intended to benefit.¹⁶ Plaintiffs' negligence per se claims based on Defendants' CSA violations are therefore proper. Defendants' Motion should be denied.

III. EVIDENCE OF DISTRIBUTORS' STATUTORY AND REGULATORY VIOLATIONS IS RELEVANT AND ADMISSIBLE EVEN IN THE ABSENCE OF A NEGLIGENCE PER SE CLAIM

As this Court previously recognized, Plaintiffs' negligence claims are properly based on the common law duty to "not expose Plaintiffs to an unreasonable risk of harm." Order on Objections to Report & Recommendation at 34 (Dkt. No. 1203). The Court observed that this duty encompasses the need to "administer responsible distribution practices." *Id.* at 35. Defendants owe this duty to Plaintiffs independent of any statutory obligations imposed on Defendants. *Id.* at 34. The Court's analysis demonstrates why Plaintiffs alleged negligence per se as an alternative basis for recovery, since negligence is itself a sufficient basis to recover.

Although Plaintiffs are not obligated to establish statutory violations in order to prevail on their negligence claim, Ohio law recognizes that one way a plaintiff may establish a defendant's negligence is to present evidence of the defendant's statutory and regulatory violations. As the Ohio Supreme Court explained, "[c]ourts view the evidentiary value of the violation of statutes imposed for public safety in three ways: as creating strict liability, as giving rise to negligence per se, or as simply evidence of negligence." *Sikora v. Wenzel*, 727 N.E.2d 1277, 1280 (2000). Thus, even in the absence of strict liability or negligence per se, statutory violations constitute evidence of negligence from which a jury may determine the applicable standard of care and whether there was a breach of that standard.

¹⁶ The fact that Cuyahoga and Summit Counties are among the intended beneficiaries of the CSA does not mean that they are authorized to enforce the CSA. On the contrary, only federal authorities can investigate and prosecute violations of federal law. See *In re Persivo*, 522 F.2d 41, 54 (2d Cir. 1975); 28 U.S.C. § 547.

Moreover, while Distributors argue that regulations may not serve as the basis for a negligence per se claim, no such limitation applies when using regulatory violations as evidence of negligence. *Chambers*, 697 N.E.2d at 203 (Ohio 1998) (violation of an administrative rule is admissible as evidence of negligence); *Stephens v. A-Able Rents Co.*, 654 N.E.2d 1315, 1320 (Ohio Ct. App. 1995) (generally accepted that regulations are admissible as bearing on the question of lack of ordinary care).

Plaintiffs are therefore permitted to present evidence of statutory and regulatory obligations imposed on Defendants in order to argue that these obligations provide evidence of the standard of care for the Defendants' underlying common law duty. More specifically, the statutes and regulations constitute evidence of how a reasonable distributor of dangerous drugs should act under the circumstances. Evidence of Defendants' violations of these statutes and regulations likewise constitutes evidence that Defendants breached the standard of care. These principles apply even if the Court were to rule that Plaintiffs are unable to satisfy the elements for negligence per se.

CONCLUSION

For the foregoing reasons, this Court should deny Distributor Defendants' Motion for Summary Judgment on Plaintiffs' Negligence Per Se Claims.

Dated: July 31, 2019

Respectfully submitted,

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